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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,817	11/04/2003	J. Christopher Flaherty	59249-163 (INSL-117DV)	6254
36310	7590	08/25/2005	EXAMINER	
INSULET CORPORATION 9 Oak Park Drive Bedford, MA 01730			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,817

Applicant(s)

FLAHERTY, J. CHRISTOPHER

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 9-14, 16, 17, 19-22 and 24-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 15, 18 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/15/03 1/22/04 4/26/04
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 51, 1, 2, 3, 15, 18, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by CHOI (US Patent No. 6,572,585). Choi discloses a system for delivering a fluid to a patient including a delivery device having a reservoir, plunger, guide means to prevent rotation of the plunger 51, 25, dispenser and a processor for controlling the dispenser based on flow instructions from a wireless remote controller (col. 2, line 34 - col. 3, line 61; figs. 4-8, 22, and 24). The wireless remote control includes a transmitter and receiver to communicate with the transmitter and receiver of the control processor and a control unit (fig. 20). The housing for the processor does not contain user input components, which are part of the wireless remote controller (col. 8, ll. 5-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHOI ('585) in view of PATALANO (US Patent No. 5,573,342). Choi discloses the claimed invention except for making the lead screw plastic. Patalano discloses a fluid delivery system using a reservoir, plunger, and plastic lead screw. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Patalano to use a plastic lead screw in the system of Choi in order to keep the system weight low for efficient and easy use by a patient.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over CHOI ('585) in view of CHOI (US Patent No. 5,993,423). Choi ('585) discloses the claimed invention except is silent concerning making a threaded insert (54,55) a different material than the plunger 22. Choi ('423) suggests making the insert 154 and plunger 122 of different materials. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Choi ('423) in the system of Choi ('585) in order to facilitate the workings of the delivery device in using different materials throughout the system based on material properties to use materials best suited for different operations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51, 1-3, 15, 18, and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 11, 34, 35, 54, 55, 73, and 74 of U.S. Patent No. 6,656,159 and claims 14, 15, 18, 32, 40, 41, 64, 65, 85, 86, 123, and 124 of U.S. Patent No. 6,656,158. Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 21, and 23-26 of U.S. Patent No. 6,740,059 and claims 13 and 14 of U.S. Patent No. 6,723,072. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all recite a fluid delivery system having a reservoir, plunger, dispenser, wireless transmitter/receiver and remote control having processor, transmitter, and receiver. Patents '159 and '158 also disclose a lead screw to advance the plunger.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. NEFTEL (US Patent No. 5,764,159) discloses a remote control system for delivering fluids to patients

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
15 August 2005



MICHAEL J. HAYES
PRIMARY EXAMINER